DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 1, 2014

Stryker Leibinger GmbH & Co. KG
c/o Ms. Julie Schoell, M.S., RAC
Staff Regulatory Affairs Specialist
Stryker Craniomaxillofacial
750 Trade Centre Way, Suite 200
Portage, MI 49002

Re: K133461
Trade/Device Name: Stryker Universal Orbital Floor System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: July 3, 2014
Received: July 7, 2014

Dear Ms. Schoell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133461

Device Name: Stryker Universal Orbital Floor System

Indications For Use:

Intended Use:

The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

Indication for Use:

The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2014.08.01 12:27:10 -04'00'

Revised 510(k) Summary

510(k) Summary

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Date prepared: July 28, 2014

Proprietary Name: Stryker Universal Orbital Floor System

Common Name: Bone plate

Regulatory Class: Class II

Regulation Number: 872.4760 Bone Plate

Product Codes: JEY

Predicate Device: Stryker Universal Orbital Floor System, K123786

Introduction:

This Traditional 510(k) is being submitted to the FDA to grant clearance to market the Stryker Universal Orbital Floor System cleared via K123786 with the following modification.

Proposed Modification:

The Stryker Universal Orbital Floor System was cleared via K123786 for reconstruction of the floor and/or medial wall of the orbit in adult patients. This Traditional 510(k) is being submitted for the same system to expand the currently cleared Indications for Use to allow use of the device in patients 15 years of age and older. The rationale for limiting the indications to those patients 15 years of age and older is that the orbital volume has reached its adult size at that age. Except for this proposed change in indications, the device remains unchanged from its earlier cleared version.

Intended Use:

The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit.

Indications for Use:

The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.

Device Description:

The Stryker Universal Orbital Floor System includes pre-bent titanium orbital floor plates, a globe retractor and a plate holding forceps.

The pre-bent titanium plates are available in a small (L=31mm W=34mm, H=12mm) and a large size (L=35mm, W=36mm, H=16mm) along with left and right configurations. The plates can be trimmed along cutting lines and contoured to fit the specific needs of the patient.

The plates are designed based on an average anatomical model of CT-scan data taken from 300 subjects (92% Caucasian). The metadata of the 300 subjects that have been included in the generation of the average anatomical model is listed in Table 1. The selected scans were obtained from healthy subjects without any deformation of the bony orbital structures.

Table 1: Meta data of the 300 CT scans

Age [years]		Gender		Ethnic Group	
10-19	18	f	122	ca	276
20-29	19	m	178	me	3
30-39	20			xx	21
40-49	28				
50-59	36				
60-69	56				
70-79	72				
80-89	44				
90-99	6				

Age: 297 scans: age 15-95, 1 scan: age 14, 1 scan: 11, 1 scan: unknown; average age: 59 years;

Gender: 122 female (f) and 178 male (m);

Ethnic Group: 276 Caucasians (ca), 3 Middle-East (me), 21 unknown (xx)

The globe retractor is an instrument designed to allow retraction of the orbital contents off the orbital floor and walls during implantation of the above mentioned pre-bent titanium plates.

Lastly, the plate holding forceps is an instrument designed specifically for use with above mentioned pre-bent titanium plates. They facilitate the insertion and positioning of the plate within the orbit.

Comparison with the Predicate Device:

The Stryker Universal Orbital Floor System is compared to its predicate device for substantial equivalence based on the following criteria:

A. Intended Use
B. Principle of Operation
C. Technological Characteristics
D. Benefit-Risk Evaluation

A: Intended Use/Indications for Use

Table 2: Substantial Equivalence of Indications for Use

	Subject Device	Predicate Device
Intended Use	Intended Use: The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit. Indications for Use: The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in patients 15 years of age and older.	Intended Use: The Stryker Universal Orbital Floor System is intended to be used in the reconstruction of the floor and/or medial wall of the orbit Indications for Use: The Stryker Universal Orbital Floor System is indicated for the reconstructive treatment of orbital floor and/or medial wall trauma or bone excision in adult patients.

The Indications for Use statement for the Stryker Universal Orbital Floor system is not identical to the predicate device; however, the differences do not alter the therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Available evidence from the literature demonstrates that the subpopulation of patients age 15 to 21 is anatomically and physiologically identical to the population greater than 22 years of age. Both the Subject and Predicate Device have the same intended use for reconstruction of the floor and/or medial wall of the orbit.

B. Principle of Operation

The basic operational principle of the Subject Device, as well as the Predicate Device, is to reconstruct the orbital floor and/or medial wall. The fixation method of both the Subject Device and the Predicate is with screws inserted through

dedicated screw holes. The Subject Device and the Predicate Device are both permanent implants and have the same craniomaxillofacial (CMF)/orbital area of application.

C. Technological Characteristics

There is no design change; the Stryker Universal Orbital Floor System has the exact same design as the Predicate Device:

- Same patient contacting surface: orbital floor and wall
- Same area of contact and contact duration (tissue/bone/permanent implant)
- Same material: titanium
- Same design: pre-bent shape based on average anatomical model
- Same sizes and shapes as the Predicate Device
- Same mode of plate adjustment: trimming along cutting lines and bending
- Both the Subject Device and Predicate Device are provided non-sterile

D. Benefit-Risk Evaluation

The design of the device approximates the shape and dimensions of the average normal orbital floor and medial wall in order to facilitate the operative goal of restoring normal (pre-traumatic) orbital volume as accurately as possible. Additionally, this approximation simplifies the bending and fitting process for the surgeon during an orbital procedure, while still allowing the surgeon to trim and contour the material to fit the specific needs of the patient. A review of the literature shows that titanium mesh and other alloplastic implants have been used for orbital repair in a pediatric subpopulation of 15 to 21 years of age for over 25 years. In published studies on the use of permanent fixation in the craniomaxillofacial skeleton in a pediatric subpopulation of 15 to 21 years of age, only the detrimental effects on growth have been noted, with no other reported complications due to age.[1] Complications associated with the use of alloplastic material in the pediatric population were no different than the risks identified for the Subject Device, which include infection, migration, extrusion, and foreign body reaction.[2] The complication rate in this age group is not shown to be greater than that seen in the 22 and over population.[3] Based on the risk assessment and data reported in the clinical literature, any adverse events are minimized and acceptable when weighed against the benefits of the intended performance.

Substantial Equivalence Analysis:

The conclusions drawn from the comparison of the intended use, principle of operation, and technological characteristics, including the clinical performance data from the literature and benefit-risk evaluation, demonstrate that the Stryker Universal Orbital Floor System performs substantially equivalent to the Predicate Device. The differences in Indications for Use do not raise new questions of safety and effectiveness.

Clinical Testing:

There was no clinical performance testing required because the differences in Indications for Use do not raise new questions of safety and effectiveness. The clinical performance data provided in the literature on analogous reference devices supports an indication in patients 15 years of age and older.

Non-Clinical Testing:

The proposed modification does not have any impact on the performance of the device. Hence, no additional non-clinical testing has been performed. Previously conducted performance tests as described in K123786 included Verification and Validation (V&V) testing of biocompatibility, cleaning, sterilization, corrosion resistance, stability of plate, functionality over lifetime, transportation of the complete set and of packaging, an end product test and a design validation – end user test. The Stryker Universal Orbital Floor System passed all tests.

Conclusions:

The results of the non-clinical data demonstrate the Stryker Universal Orbital Floor System will perform as intended in the specified use conditions. The intended use, technological characteristics, clinical performance data presented in the literature, and the benefit-risk evaluation supports that known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of the intended performance of the device during normal conditions of use executed per the product labeling. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.

References

1. Tabrizi, R., Ozkan, T.B., Mohammadinejad, C., Minaee, N. (2010). Orbital floor reconstruction. *Journal of Craniofacial Surgery*. 21(4), 1142-6.

2. Hatton, M.P., Watkins, L.M., Rubin, P.A.D. (2001). Orbital Fractures in Children. *Ophthalmic Plastic and Reconstructive Surgery*. 17(3): 174-9.

3. Chao, M.T., Losee, J.E. (2009). Complications in Pediatric Facial Fractures. *CMF Trauma and Reconstruction*. 2(2): 103-12.